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EXAMINER

WATTS, ALLISON LEIGH

ART UNIT PAPER NUMBER

1753

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/640,985 | Applicant(s) SRINIVASAN ET AL. | |
| | Examiner Allison L. Watts | Art Unit 1753 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☒ Claim(s) 6,17,28,36 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>2/24/2004</u> . | 6) <input type="checkbox"/> Other: ____ |

Specification

1. The disclosure is objected to because of the following informalities:
2. The blanks should be filled in throughout the specification.

Appropriate correction is required.

Claim Objections

1. Claims 17 and 28 are objected to because of the following informalities:
2. As to Claim 17, the word "wired" should read as "wire."
3. As to Claim 28, the content is repetitive of the content of Claim 17.
4. Appropriate correction is required.
5. Claims 6 and 36 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claim 30 recites the limitation "the adhesive". There is insufficient antecedent basis for this limitation in the claim. For the purpose of this office action, the Examiner with assume that Claim 30 refers back to Claim 29 rather than Claim 28, so that Claim 30 should read "The apparatus of claim 29."

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 5-6, 10, 12-14, 20 and 31-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Chan et al.

As to Claims 1, 5, 14 Chan et al. disclose an apparatus for testing a sample for constituents comprising a plurality of electrochemical sensors that are adapted to detect a different constituent (Page 8, paragraph 0065, Page 2, paragraph 0018), including concentration (Page 15, paragraph 0138), within the sample, a reservoir for containing the sample, a plurality of interconnected channels fluidly coupling the reservoir to the sensors (Figure 9A, Page 8, paragraph 0070, Page 8, paragraph 0073), and a circuit coupled to the sensors to detect the presence of a constituent at each sensor (Page 11, paragraph 0096).

As to Claims 2 and 35, Chan et al. disclose using a pump to manipulate sample flow throughout the micro-channels (Page 11, paragraph 0102).

As to Claim 10, Chan et al. disclose analytic circuitry for analyzing the electrochemical properties of the sensors, a multiplexer, and circuitry for controlling the multiplexer to selectively couple the circuitry to the sensors (Page 7, paragraph 0060, Page 11, paragraph 0096).

As to Claims 12 and 13, Chan et al. disclose the analytical circuitry being electrically coupled to the working, reference, and counter electrodes (Page 15, paragraph 0140, Page 16, paragraph 0159 through Page 17, paragraph 0164) of each sensor and is adapted to apply a series of electrical pulses to the cell and measure the transient responses through the cell to each of the pulses, and then integrate each transient response to a pulse and derive electrical charge Q as a function of the magnitude of the corresponding pulse (Page 11, paragraph 0098, Page 15, paragraph 0142, Page 16, paragraphs 0150, 0156, and 0157).

As to Claim 20, Chan et al. disclose testing a sample for constituents comprising a plurality of electrochemical sensor cells (Page 2, paragraph 0018, Page 17, paragraph 0163) that are each adapted to detect a different constituent within the sample (Page 8, paragraph 0065, Page 2, paragraph 0018), analytic circuitry, a multiplexer, and control circuitry for controlling the multiplexer to selectively couple the circuitry to each of the sensors (Page 7, paragraph 0060, Page 11, paragraph 0096).

As to Claim 31, Chan et al. disclose a method for testing a sample for constituents comprising providing a plurality of electrochemical sensors (Page 2,

paragraph 0018, Page 17, paragraph 0163) that are each adapted to detect a different constituent within the sample (Page 8, paragraph 0065, Page 2, paragraph 0018), providing a circuit coupled to the sensors to analyze the electrochemical properties of the sensors in order to detect the presence of a particular constituent (Page 11, paragraph 0096), introducing a sample into each sensor, and simultaneously analyzing the electrical properties of each sensor to detect the presence of at least one constituent at each sensor (Page 11, paragraph 0095, Page 17, paragraph 0164).

As to Claims 32-34 and 36 Chan et al. disclose each sensor comprising a working electrode with a coating selected to bind with a particular electro-active constituent within a sample (Page 8, paragraph 0065), counter and reference electrodes, (Page 15, paragraph 0140, Page 16, paragraph 0159 through Page 17, paragraph 0164) and wherein the working electrode of each sensor has a different coating that enables the detection of a different constituent at each sensor (Page 2, paragraph 0018), as well as providing a reservoir for containing the sample, and providing a plurality of interconnected channels fluidly coupling the reservoir the sensors, and whereby each sample in each sensor is part of the same larger sample (Page 8, paragraph 0070).

As to Claim 37, Chan et al. disclose introducing a different sample to each sensor (Page 4, paragraph 0033).

As to Claims 38 and 39, Chan et al. disclose simultaneously determining the concentrations (Page 15, paragraph 0138) of the constituents in the sample at each sensor, as well as analyzing each sensor sequentially (Page 11, paragraph 0095).

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As to Claims 40 and 41, Chan et al. disclose each sensor comprising a working electrode with a coating selected to bind with a particular electro-active constituent (Page 8, paragraph 0065), counter and reference electrodes (Page 15, paragraph 0140, Page 16, paragraph 0159 through Page 17, paragraph 0164), and wherein detecting a constituent in the sample comprises selectively electrically coupling the circuit to the working, reference, and counter electrodes of a sensor, applying a series of electrical pulses to the cell, and measuring the electrical response by the cell responsive to each of the pulses (Page 11, paragraph 0098, Page 15, paragraph 0142, Page 16, paragraphs 0150, 0156, and 0157).

Claim Rejections - 35 USC § 103

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al., as applied to Claim 2, in view of Lin et al.

Chan et al. disclose using a pump to manipulate sample flow throughout the micro-channels (Page 11, paragraph 0102).

Chan et al. do not disclose using a micro-pump.

Lin et al. disclose using micro-pumps (46, 48) to assist in the flow of sample from a reservoir and towards a mixing channel leading to an electrochemical cell (Figure 2, Claim 18, Column 4, lines 15-21).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the testing apparatus as disclosed by Chan et al. by using micro-pumps rather than pumps because the apparatus is micro-scale including micro-channels.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al., as applied to Claim 2, in view of Simpson et al.

Chan et al. disclose using temperature to determine the identity of a particular base in a target nucleic acid (Page 12, paragraph 0109).

Chan et al. do not disclose using a micro-heater coupled to each sensor.

Simpson et al. disclose a reactor array with micro-passages with a micro-heater disposed on each reactor in order to control the reactions taking place within each reactor (Column 5, lines 31-52).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the testing apparatus as disclosed by Chan et al. by using micro-heaters because the apparatus is micro-scale and a heating element would assist in the detection of target analytes in the sample.

6. Claims 7, 15, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al., as applied to Claims 1 and 20, in view of Olson.

As to Claims 7 and 27:

Chan et al. disclose the electrochemical sensors each comprising an electrochemical cell (Page 17, paragraph 0157, Page 17, paragraph 0163) including a working electrode with a coating selected to bind with a particular electro-active constituent (Page 8, paragraph 0065), counter and reference electrodes (Page 15, paragraph 0140, Page 16, paragraph 0159 through Page 17, paragraph 0164), as well as adding filters to the device (Page 11, paragraph 0095) and using electrolyte solutions in contact with the electrodes (Page 15, paragraph 0139, Page 2, paragraph 0015).

Chan et al. does not disclose a filter paper that separates the electrodes from each other, or the filter paper containing an electrolyte Chan et al.

Olson discloses an electrochemical cell (Column 1, lines 15-19) with an electrolyte supplied to a filter disc, and the filter disc, or porous medium, positioned between the counter and sensing electrodes (Column 2, line 61 through Column 3, line 4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrochemical cell as disclosed by Chan et al. by positioning filter paper containing an electrolyte between the electrodes as disclosed by Olson because an electrolyte solution would assist in conduction to produce an electrical signal, and the filter paper would absorb an electrolyte solution.

As to Claim 27:

Chan et al. further discloses each working electrode having a coating so that each sensor tests for the same constituent (Page 13, paragraph 0125).

As to Claim 15:

Chan et al. disclose the working electrode is adapted to bind with many different types of proteins (Page 4, paragraphs 0036 and 0038),

7. Claims 8 and 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al. and Olson, as applied to Claim 7, in view of Peat et al. and Warren et al.

As to Claim 8:

Chan et al. does not disclose the electrochemical cell comprising a glass frit between the channels external of the sensor and the electrodes, and a capillary housing the other elements of the sensor.

Peat et al. disclose an electrical sensor module comprising at least one electrochemical sensor, with a micro-porous barrier to separate each of the electrochemical sensors from the environment of the sensor module (Column 1, lines 21-27), where the micro-porous barrier could be a glass frit, which would dislodge any fouling material (Column 1, lines 36-43).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrochemical cell as disclosed by Chan et al. and Olson by having a glass frit separate the external environment from the electrodes as disclosed by Peat et al. because it would dislodge fouling material.

Warren et al. disclose an electrochemical cell (80) with a cylindrical glass housing (82) (Figure 4A, Page 4, paragraph 0035).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrochemical cell as disclosed by Chan et al. and Olson by having a cylindrical housing as disclosed by Warren et al. contain the

elements in the sensor and protect them from interacting with the surrounding environments.

As to Claim 9:

Chan et al. disclose the one of two electrodes disposed furthest from the channel through which sample enters the sensor, and a second electrode disposed closest to the channel through which sample enters the sensor, and the reference electrode disposed between them (Figures 1 and 2, Page 17, paragraph 0163).

Chan et al. does not disclose a capillary housing with an opening adjacent the working electrode for excess sample to exit the cell.

Warren et al. further discloses a liquid filling hole (94) that allows for testing and drainage of testing solutions from the electrochemical cell (Figure 4A, Page 4, paragraph 0035).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrochemical cell as disclosed by Chan et al. and Olson by having a hole adjacent the working electrode as disclosed by Warren et al. because it allows for drainage of a testing solution from the electrochemical cell.

8. Claims 11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al., as applied to Claims 10 and 20, in view of Cliffel et al. and Marks et al.

Chan et al. disclose a using a circuit board or chip and a multiplexer (Page 11, paragraph 0096).

Chan et al. do not disclose circuitry, a multiplexer, and control circuit on a micro-circuit chip.

Cliffel et al. disclose electrochemically detecting at least one analyte in a sample using electrodes in a chamber (Page 2, paragraphs 0018 and 0019), where a micro-circuit may be used (Page 11, paragraph 0191), and multiplex reactions may be performed on the micro-circuit (Column 7, lines 53-65).

Marks et al. disclose a micro-circuit system with an array of micro-electrodes for performing binding reactions on a sample (Abstract, Column 11, lines 56-64).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrochemical sensor as disclosed by Chan et al. by using a micro-circuit as disclosed by Cliffel et al. and Marks et al. because the electrochemical apparatus disclosed by Chan et al. is micro-scale and contains micro-channels.

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al. and Olson, as applied to Claim 15, in view of Snow et al.

Chan et al. disclose a coating disposed on the electrodes for binding with target molecules (Page 17, paragraph 0164).

Chen et al. do not disclose the coating comprising dithiol.

Snow et al. disclose a chemical sensor that uses dithiol as a coupling agent on a thin film that comprises electrodes (Column 6, line 55 through Column 7, line 29).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrodes disclosed by Chan et al. by providing a dithiol coating on the electrodes as disclosed by Snow et al. because it enables the

build-up of thiols to form a resistant, multilayered film, in which variations in the deposition may be controlled (Column 7, lines 4-19).

10. Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al., Cliffel et al., and Marks et al., as applied to Claim 21, in view of Olson.

As to Claim 22:

Chan et al. disclose the electrochemical sensors each comprising an electrochemical cell (Page 17, paragraph 0157, Page 17, paragraph 0163) including a working electrode with a coating selected to bind with a particular electro-active constituent (Page 8, paragraph 0065), counter and reference electrodes (Page 15, paragraph 0140, Page 16, paragraph 0159 through Page 17, paragraph 0164), as well as adding filters to the device (Page 11, paragraph 0095) and using electrolyte in contact with the electrodes (Page 15, paragraph 0139, Page 2, paragraph 0015). Chan et al. does not disclose a filter paper that separates the electrodes from each other, or the filter paper containing an electrolyte Chan et al.

Chan et al. do not disclose a filter paper that separates the electrodes from each other, or the filter paper containing an electrolyte Chan et al.

Olson discloses an electrochemical cell (Column 1, lines 15-19) with an electrolyte supplied to a filter disc, and the filter disc, or porous medium, positioned between the counter and sensing electrodes (Column 2, line 61 through Column 3, line 4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrochemical cell as disclosed by Chan et al. by

positioning filter paper containing an electrolyte between the electrodes as disclosed by Olson because an electrolyte solution would assist in conduction to produce an electrical signal, and the filter paper would absorb an electrolyte solution.

As to Claims 23 and 24:

Chan et al. disclose the analytical circuitry being electrically coupled to the working, reference, and counter electrodes (Page 15, paragraph 0140, Page 16, paragraph 0159 through Page 17, paragraph 0164) of each sensor and is adapted to apply a series of electrical pulses to the cell and measure the transient responses through the cell to each of the pulses, and then integrate each transient response to a pulse and derive electrical charge Q as a function of the magnitude of the corresponding pulse (Page 11, paragraph 0098, Page 15, paragraph 0142, Page 16, paragraphs 0150, 0156, and 0157).

As to Claim 25:

Chan et al. disclose detecting the concentration of the constituent in the sample (Page 15, paragraph 0138).

11. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al., Cliffel et al., and Marks et al., as applied to Claim 21, in view of Simpson et al.

Chan et al. disclose using temperature to determine the identity of a particular base in a target nucleic acid (Page 12, paragraph 0109).

Chan et al. do not disclose using a micro-heater coupled to each sensor.

Simpson et al. disclose a reactor array with micro-passages with a micro-heater disposed on each reactor in order to control the reactions taking place within each reactor (Column 5, lines 31-52).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the testing apparatus as disclosed by Chan et al. by using micro-heaters because the apparatus is micro-scale and a heating element would assist in the detection of target analytes in the sample.

12. Claims 17 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al., Olson, and Snow et al., as applied to Claim 16, in view of Bruckenstein et al., Porter et al., and Srinivasan et al.

Chan et al. disclose the electrodes having one of many possible shapes and sizes (Page 7, paragraph 0054 and 0057).

Chan et al. do not disclose a working electrode comprising a 25 to 100 micron diameter, 1 meter long gold wire coiled around a 0.25 to 0.5 millimeter diameter gold support wire.

Bruckenstein et al. disclose using a gold coiled wire for an auxiliary electrode in order to have sufficient area to keep the cell resistance low enough to provide the necessary current requirements (Column 7, lines 64-68),

Porter et al. disclose using a gold wire as the working electrode in an electrochemical cell (Column 13, lines 53-57).

Srinivasan et al. disclose adjusting the size and shape of electrodes in order to create any cell constant and that varying the current allows for use of the sensor in various applications (Page 3, paragraph 0029).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrodes as disclosed by Chan by altering the size and shape of the electrodes and using a gold wire coil as disclosed by Bruckenstein et al., Porter et al., and Srinivasan et al. because the exact size and shape of the electrodes used may vary slightly depending on the geometry of the electrochemical cell and the exact application in which it is being used, as long as they are microscale. It would also be obvious to provide a support wire for a 1 meter long coil.

13. Claims 18-19 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan et al., Olson, and Snow et al., as applied to Claims 16, 18, 22, and 29 in view of Senda et al..

Chan et al. disclose the preferred electrodes being gold electrodes (Page 7, paragraph 0056).

Chan et al. do not disclose that the working electrode may be a powdered gold bound together by adhesive being a carbon powder and tetraflourethylene adhesive.

Senda et al. disclose an enzyme electrode made by combining a noble metal, such as gold, (Column 4, lines 16-31) with graphite powder and a non-polar binder, such as Teflon (tetraflourethylene) paste (Column 4, lines 45-51).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrodes as disclosed by Chan by using a

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powdered gold and graphite bounded by polytetrafluorethylene as disclosed by Senda et al. because of the ease of forming the electrode.

Conclusion


14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6485690 B1, US 6187164 B1, US 6942771 B1, US 20020157947 A1, US 5603351 A, US 6123820 A, US 20040043479 A1, US 4874500 A, US 6376233 B1, US 6716642 B1, US 6630359 B1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison L. Watts whose telephone number is (571) 272-6640. The examiner can normally be reached on Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALW
12/15/2006



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